## **Complete Summary**

#### **GUIDELINE TITLE**

SAGES guidelines for the use of laparoscopic ultrasound.

## **BIBLIOGRAPHIC SOURCE(S)**

Society of American Gastrointestinal and Endoscopic Surgeons (SAGES). SAGES guidelines for the use of laparoscopic ultrasound. Los Angeles (CA): Society of American Gastrointestinal and Endoscopic Surgeons (SAGES); 2009 Mar. 35 p. [82 references]

## **GUIDELINE STATUS**

This is the current release of the guideline.

## **COMPLETE SUMMARY CONTENT**

**SCOPE** 

 $\label{eq:methodology-including Rating Scheme and Cost Analysis} \\$ 

RECOMMENDATIONS

EVIDENCE SUPPORTING THE RECOMMENDATIONS

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

QUALIFYING STATEMENTS

IMPLEMENTATION OF THE GUIDELINE

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT

**CATEGORIES** 

IDENTIFYING INFORMATION AND AVAILABILITY

**DISCLAIMER** 

## SCOPE

## **DISEASE/CONDITION(S)**

Any disease or condition that may benefit from the use of laparoscopic ultrasound, including:

- Adrenal disease
- Biliary disease
- Esophagogastric cancer
- Gastric cancer
- Gynecologic conditions (ovarian or uterine masses, cervical carcinoma)
- Kidney disease
- Liver disease
- Pancreatic disease

## **GUIDELINE CATEGORY**

Diagnosis Evaluation

## **CLINICAL SPECIALTY**

Gastroenterology Nephrology Obstetrics and Gynecology Oncology Radiology Surgery

## **INTENDED USERS**

**Physicians** 

## **GUIDELINE OBJECTIVE(S)**

To provide current recommendations in the use and benefits of laparoscopic ultrasound (LUS) for the surgeon

## **TARGET POPULATION**

Patients undergoing surgery for adrenal disease, biliary disease, esophagogastric cancer, gastric cancer, gynecologic disease, kidney disease, liver disease, and adenocarcinoma of the pancreas

#### INTERVENTIONS AND PRACTICES CONSIDERED

Laparoscopic ultrasound

## **MAJOR OUTCOMES CONSIDERED**

- Diagnostic accuracy: sensitivity and specificity
- Complication rates
- Disease recurrence rates
- Operative time
- Length of hospital stay
- Conversion rates
- Unnecessary laparotomy rate
- Cost

## **METHODOLOGY**

## METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Secondary Sources) Searches of Electronic Databases

## DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

A systematic literature search of MEDLINE for the period 1966 through May 15, 2007, limited to English language articles, identified 146 relevant reports. The search strategy used the terms "laparoscopic ultrasound," "ultrasound training," "ultrasound biliary," "ultrasound pancreas," "ultrasound adrenal," "ultrasound liver," "ultrasound gynecology," "ultrasound kidney," and "ultrasound stomach."

The articles were divided into the following categories:

- Randomized studies, meta-analyses, and systematic reviews
- Prospective studies
- Retrospective studies
- Case reports
- Review articles

All case reports, old reviews, and smaller studies were excluded.

The reviewers manually searched the bibliographies for additional articles that may have been missed in the original search.

## **NUMBER OF SOURCE DOCUMENTS**

Not stated

## METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

## RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

## **Levels of Evidence**

**Level I**: Evidence from properly conducted randomized, controlled trials.

**Level II**: Evidence from controlled trials without randomization; cohort or case-control studies; multiple time series; dramatic uncontrolled experiments.

**Level III**: Descriptive case series; opinions of expert panels.

## METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses Systematic Review

#### **DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE**

To maximize the efficiency of the review, the articles were divided in the following subject categories:

- Training
- Technical
- Liver
- Hepatobiliary
- Gynecology
- Adrenal
- Pancreas
- Kidney
- Stomach
- Miscellaneous topics

Reviewers graded the level of each article (see "Rating Scheme for the Strength of the Evidence").

#### METHODS USED TO FORMULATE THE RECOMMENDATIONS

**Expert Consensus** 

# DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

## RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

## **Grades of Recommendations**

**Grade A**: Based on high level (Level I or II), well-performed studies with uniform interpretation and conclusions by the expert panels.

**Grade B**: Based on high level, well-performed studies with varying interpretations and conclusions by the expert panels.

**Grade C**: Based on lower level evidence (Level II or less) with inconsistent findings and/or varying interpretations or conclusions by the expert panels.

#### COST ANALYSIS

Published cost analyses were reviewed.

The literature suggests that for pancreatic adenocarcinoma, staging laparoscopy with laparoscopic ultrasound is more cost-effective than open exploration if its yield is at least 30%.

## METHOD OF GUIDELINE VALIDATION

Internal Peer Review

## **DESCRIPTION OF METHOD OF GUIDELINE VALIDATION**

The guideline was reviewed and approved by the Board of Governors of the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES), March 2009.

## **RECOMMENDATIONS**

## **MAJOR RECOMMENDATIONS**

Definitions of the levels of evidence (**I, II, III**) and the grades of the recommendations (**A, B, C**) are provided at the end of the "Major Recommendations" field.

## Guidelines for the Use of Laparoscopic Ultrasound (LUS) in Gastric Cancer

LUS for the staging of gastric cancer patients can be performed safely, adds little time to the duration of staging laparoscopy, and does not increase significantly patient morbidity (**Grade A**). The routine use of staging laparoscopy and LUS after a negative preoperative work-up (computed tomography [CT] with or without endoscopic ultrasound [EUS]) is recommended (**Grade B**).

## Guidelines for the Use of Laparoscopic Ultrasound in Esophagogastric Cancer

Because of the limited quality of the available evidence (**Level III**) showing a benefit of staging laparoscopy and the absence of clear description of the additional benefit of LUS in this setting, the ability to provide a strong recommendation for the routine use of LUS in pretherapeutic staging of esophageal cancer is limited. Nevertheless, diagnostic laparoscopy (DL) with ultrasound should be considered in patients with esophagogastric malignancies who do not have metastatic disease on high quality staging CT scan (**Grade C**).

## Guideline for the Use of Laparoscopic Ultrasound in Adrenal Surgery

LUS as an adjunct to laparoscopic adrenalectomy has benefits in selected cases (**Grade C**). It can assist in localizing the gland when it is hidden within retroperitoneal adipose tissue (**Grade B**), localizing the adrenal vein (**Grade C**), and assessing invasion (**Grade C**).

## Guideline for the Use of Laparoscopic Ultrasound in Biliary Disease

LUS is a good alternative to intraoperative cholangiogram ( $\mathbf{Grade}\ \mathbf{B}$ ). Compared to intraoperative cholangiogram, it costs less to perform ( $\mathbf{Grade}\ \mathbf{B}$ ) and takes less time ( $\mathbf{Grade}\ \mathbf{C}$ ).

## Guidelines for the Use of Laparoscopic Ultrasound in Gynecologic Procedures

LUS can be used in early cervical carcinoma to help identify metastasis (**Grade C**). Although, small series of LUS have demonstrated reasonable diagnostic accuracy compared to other radiologic studies, further research is needed to

determine the true value of LUS (**Grade C**). LUS may also be useful in the identification of myomas of the uterus (**Grade C**). Generally, there is a paucity of literature in this area and firm recommendations cannot be made.

## Guideline for the Use of Laparoscopic Ultrasound in Kidney Disease

LUS is useful for intraoperative localization of deep anatomical structures that are not obvious on visual inspection during kidney surgery (**Grade C**). This feature may help improve patient safety by helping the surgeon avoid injuries to structures such as the ureters or the renal or iliac vessels (**Grade C**).

## **Guidelines for the Use of Laparoscopic Ultrasound in Liver Disease**

LUS is useful for staging of hepatocellular and metastatic colon and rectal cancers and can help guide treatment or avoid unnecessary open operations (**Grade B**) and detect metastasis from other cancers (**Grade C**).

## Guidelines for the Use of Laparoscopic Ultrasound for the Pancreas

LUS can be performed safely in patients with pancreatic adenocarcinoma and other pancreatic diseases (**Grade B**). LUS provides additional prognostic information to DL in a fraction of examined patients with pancreatic adenocarcinoma and further decreases the rate of unnecessary laparotomies (**Grade C**). Based on the available evidence, selective rather than routine use of the procedure for pancreatic cancer staging may be better justified and more cost-effective (**Grade C**). LUS is also useful in other pancreatic diseases and can help localize and guide the resection of tumors such as insulinomas (**Grade C**). Further, better quality studies needed to document the value of LUS for the management of pancreatic disease.

#### Definitions:

## **Levels of Evidence**

**Level I**: Evidence from properly conducted randomized, controlled trials.

**Level II**: Evidence from controlled trials without randomization; cohort or case-control studies; multiple time series; dramatic uncontrolled experiments.

**Level III**: Descriptive case series; opinions of expert panels.

## **Grades of Recommendation**

**Grade A**: Based on high level (Level I or II), well-performed studies with uniform interpretation and conclusions by the expert panels.

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**Grade C**: Based on lower level evidence (Level II or less) with inconsistent findings and/or varying interpretations or conclusions by the expert panels.

## **CLINICAL ALGORITHM(S)**

None provided

## **EVIDENCE SUPPORTING THE RECOMMENDATIONS**

#### TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (see "Major Recommendations").

## BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

#### **POTENTIAL BENEFITS**

Appropriate use of laparoscopic ultrasound during surgery to localize and stage disease, as well as to decrease the rate of negative laparotomies, other procedures, and associated morbidity

## **POTENTIAL HARMS**

In general, complications of diagnostic laparoscopic ultrasound are uncommon. Most complications are due to the associated surgical procedures.

## **QUALIFYING STATEMENTS**

## **QUALIFYING STATEMENTS**

## **Disclaimer**

Clinical practice guidelines are intended to indicate the best available approach to medical conditions as established by systematic review of available data and expert opinion. The approach suggested may not be the only acceptable one given the complexity of the health care environment. These guidelines are intended to be flexible, as the surgeon must always choose the approach best suited to the patient and to the variables in existence at the time of the decision. These guidelines are applicable to all physicians who are appropriately credentialed and address clinical situations regardless of specialty.

## **Limitations of the Available Literature**

Use of Laparoscopic Ultrasound (LUS) in Gastric Cancer

All of the studies are retrospective reviews of collected data, but they do show a significant decrease in negative laparotomy rates. Another limitation is the difficulty in quantifying the added benefit of LUS over routine diagnostic laparoscopy (DL), though as mentioned above, there seem to be some advantages. One study reports that LUS added additional information (over

laparoscopy alone) in 1 out of the 28 patients who had unresectable disease as determined by staging laparoscopy.

Use of LUS in Kidney Disease

The sparseness of available studies and their inadequate quality limit the ability to provide firm recommendations.

Use of LUS for the Pancreas

The quality of the available studies on the use of LUS for patients with pancreatic disease is limited, as no Level I evidence exists. Furthermore, the majority of studies are single-institution reports from highly specialized centers, making generalizations difficult and allowing institutional and personal biases to be introduced into the results.

In addition, reported data are not uniform across studies, making analysis difficult. A number of studies do not report the diagnostic accuracy of LUS separately from DL, and other studies do not specify the quality of preoperative imaging, the criteria used to define resectability, and the number of R0 resections. Importantly, studies often evaluate nonhomogeneous patient samples—including patients with localized and locally advanced pancreatic cancers, with periampullary and other nonpancreatic cancers or even with benign disease—do not report results separately.

## **IMPLEMENTATION OF THE GUIDELINE**

## **DESCRIPTION OF IMPLEMENTATION STRATEGY**

An implementation strategy was not provided.

# INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

#### **IOM CARE NEED**

Getting Better

## **IOM DOMAIN**

Effectiveness

## **IDENTIFYING INFORMATION AND AVAILABILITY**

## **BIBLIOGRAPHIC SOURCE(S)**

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American Gastrointestinal and Endoscopic Surgeons (SAGES); 2009 Mar. 35 p. [82 references]

#### **ADAPTATION**

Not applicable: The guideline was not adapted from another source.

#### **DATE RELEASED**

2009 Mar

## **GUIDELINE DEVELOPER(S)**

Society of American Gastrointestinal and Endoscopic Surgeons - Medical Specialty Society

## **SOURCE(S) OF FUNDING**

Society of American Gastrointestinal and Endoscopic Surgeons (SAGES)

#### **GUIDELINE COMMITTEE**

SAGES Guidelines Committee

## **COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE**

Committee Members: William Richardson, MD (Co-Chair); Dimitrios Stefanidis, MD; Sumeet Mittal, MD; Keith Apelgren, MD; Ronald Clements, MD; David Earle, MD; Timothy Farrell, MD; Stephen Haggerty, MD; Jeffrey Hazey, MD; Steven Heneghan, MD; Geoffrey Kohn, MD; James Korndorffer, MD; Lisa Martin Hawver, MD; D. Wayne Overby, MD; Patrick Reardon, MD; William Reed, MD; Matthew Ritter, MD; Alan Saber, MD; Julio Teixeira, MD; Melina Vassiliou, MD; Andrew Wright, MD; Robert Fanelli, MD (Chair)

## FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Members of the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) disclose potential conflicts of interest and pertinent financial relationships prior to serving as faculty for SAGES-sponsored educational events, delivering presentations at scientific meetings, etc. Additionally, members of SAGES Committees disclose their potential conflicts of interest and pertinent financial relationships annually as a condition of committee membership.

#### **GUIDELINE STATUS**

This is the current release of the guideline.

#### **GUIDELINE AVAILABILITY**

Electronic copies: Available from the <u>Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) Web site</u>.

Print copies: Available from the Society of American Gastrointestinal Endoscopic Surgeons (SAGES), 11300 W. Olympic Blvd., Suite 600, Los Angeles, CA 90064;

Web site: www.sages.org.

#### **AVAILABILITY OF COMPANION DOCUMENTS**

None available

#### **PATIENT RESOURCES**

None available

#### **NGC STATUS**

This summary was completed by ECRI Institute on March 5, 2010.

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